

COMPARATIVE COST OF ABLATION IN ATRIAL FIBRILLATION PATIENTS STRATIFIED BY PROCEDURAL SUCCESS VERSUS FAILURE: IMPLICATIONS FOR RESOURCE UTILIZATION IN MEDICARE-AGED ABLATION CANDIDATES IN THE UNITED STATES

Kim MH¹, Lin J², Foltz Boklage SH³, Kreilick CA³

¹Northwestern University, Chicago, IL, USA, ²sanofi-aventis U.S., Bridgewater, NJ, USA,

³ProUnlimited, Boca Raton, FL, USA

OBJECTIVES: Catheter ablation is increasingly used to maintain sinus rhythm in atrial fibrillation (AF) patients unresponsive to antiarrhythmic drugs (AADs). We compared medical costs in Medicare-aged AF patients following successful *vs* unsuccessful ablation. **METHODS:** In this retrospective study, AF pts with 1) an index ablation; 2) ≥ 12 months' medical/pharmacy coverage pre- and post-index; 3) ≥ 2 AF inpatient/outpatient visits within 6 months and AAD treatment within 12 months of index ablation were identified from the MarketScan® Medicare database (January 2002-June 2007). Ablation success was defined as absence of AAD treatment 6-12 months post ablation. **RESULTS:** A total of 135 AF patients (67% men, mean 73 yrs) were included; ablation was successful in 69 and failed in 66 patients. Most patients (97% with successful *vs* 94% with failed ablation) underwent only 1 ablation procedure during the 12-month study. After successful ablation, patients discontinued AAD in (mean) 54 days. Use of rate-control and anticoagulant drugs declined after successful ablation (67% *vs.* 87% and 64% *vs.* 86% patients, respectively), but remained largely undiminished after failed ablation (70% *vs.* 74% and 82% *vs.* 88% patients, respectively). Mean (median) per-patient costs per ablation were \$13,655 (\$11,795) for successful *vs.* \$17,294 (\$11,778) for failed ablation. Other AF-related costs over 1 yr post index ablation were \$2394 (\$7677) for successful *vs.* \$2703 (\$4478) for failed ablation patients. Overall annual per-patient costs were lower in patients with successful (mean \$16,049; median \$17,135) *vs.* failed (\$19,997; \$26,635) ablation ($P = 0.07$). **CONCLUSIONS:** Ablation failed in half of 'real-world' Medicare-aged AF patients, and few underwent repeat ablation. Overall costs were higher for failed *vs* successful ablation patients, possibly because of differences in AF-related issues, complications, and ablation methods. Over time, this cost differential would likely increase if failed ablation patients underwent repeat procedures. Identification of predictors for ablation success may reduce medical costs.

PODIUM SESSION III: PERSONALIZED MEDICINE STUDIES

RISK-BENEFIT FRAMEWORK FOR EVALUATION OF GENE EXPRESSION PROFILING IN WOMEN WITH EARLY STAGE BREAST CANCER: A DECISION MODEL DEVELOPED IN COLLABORATION WITH STAKEHOLDERS

Roth J, Veenstra D

University of Washington, Pharmaceutical Outcomes Research and Policy Program, Seattle, WA, USA

OBJECTIVES: To develop a parsimonious risk-benefit model to assist stakeholders in evaluating gene expression profiling (GEP) to guide use of adjuvant chemotherapy in early stage breast cancer compared to clinical guidelines. **METHODS:** A decision model was developed to estimate comparative benefits and harms of using GEP relative to NCCN guidelines, including disease recurrences, adverse events, life years, and quality-adjusted life years (QALYs). Model structure and output were developed through a collaborative feedback process with stakeholders. The model's interactive structure allows users to specify the GEP, adjuvant chemotherapy regimen, and prognostic and predictive risk stratification. A Markov process was utilized to estimate clinical outcomes, and parameter uncertainty was evaluated through one-way and probabilistic sensitivity analysis. The base case patient was a pre-menopausal woman of age 44. The prognostic and predictive properties of the GEPs were derived from published retrospective analyses of RCTs. Adjuvant chemotherapy regimen-specific utility decrements were incorporated based on trial-based adverse event rates. **RESULTS:** Preliminary analyses indicate that a GEP that provides prognostic information only would identify 61% of women to receive adjuvant chemotherapy, while 96% would be identified by clinical guidelines. Based on these estimates, GEP and clinical guidelines would prevent 29% and 34% of distant recurrences, respectively. These findings suggest that GEP may lead to a net harm, with 9.86 QALYs for GEP versus 10.08 for clinical guidelines, due to increased risk of disease recurrence, despite the avoidance of chemotherapy and side effects in 39% of women. Analyses of other risk stratification approaches are ongoing. **CONCLUSIONS:** We found that use of GEP to guide use of adjuvant chemotherapy in early stage breast cancer could lead to a decrease in QALYs relative to the use of clinical guidelines if chemotherapy predictive information is not available. Ongoing efforts are focused on collaboration with stakeholders to align model structure and output with stakeholder needs.

EFFECTS OF PRIMARY PROPHYLACTIC G-CSF USE AND DURATION OF USE ON NEUTROPENIA HOSPITALIZATIONS FOR ELDERLY BREAST CANCER PATIENTS RECEIVING CHEMOTHERAPY

Rajan SS¹, Lyman G²

¹University of Houston, Houston, TX, USA, ²Duke University, Durham, NC, USA

OBJECTIVES: Systemic chemotherapy is a vital component of breast cancer management. However early-onset chemotherapy-toxicities like neutropenia hinder chemotherapy use in breast cancer patients, especially in the elderly. Depending on the

severity, neutropenia management requires hospitalization and aggressive systemic antibiotic administration, and involves reduction or discontinuation of chemotherapy. Primary prophylactic granulocyte-colony stimulating factors (PPG-CSF), especially when administered over adequate duration, help prevent neutropenia. Nevertheless, evidence supporting the effectiveness of PPG-CSF in the elderly is limited, and thus the ASCO guidelines for PPG-CSF use and specifications for duration of its use in the elderly are not explicit. This study analyzed the effects of PPG-CSF and adequate duration of PPG-CSF on the occurrence of chemotherapy-induced neutropenia hospitalizations in elderly breast cancer patients. **METHODS:** A retrospective observational study for patients newly diagnosed with primary breast cancer between the years 1994 to 2002 using the SEER-Medicare data was performed. To account for the non-random nature of the observational data a non-parametric covariate genetic matching technique was used to pre-process the data before performing logistic regressions to estimate the treatment effects. **RESULTS:** Administration of PPG-CSF during the first course of chemotherapy reduced neutropenia hospitalizations by 15% within the first three months and 16% within the first six months of chemotherapy initiation ($p < 0.05$). Hospitalizations within the first three months of chemotherapy initiation were three times higher in women receiving less than five consecutive days of PPG-CSF compared to women receiving PPG-CSF for five or more days ($p < 0.05$). Hospitalizations within the first one and six months were also considerably lower with longer PPG-CSF duration (≥ 5 days) ($p < 0.10$). **CONCLUSIONS:** PPG-CSF use is associated with reduction in occurrence of severe neutropenia and reduced in-patient health care utilization. These findings have implications for ASCO guidelines and Medicare coverage policies for PPG-CSF administration and duration of administration in elderly breast cancer patients.

ECONOMIC EVALUATION OF GENETIC TEST IN COMBINATION WITH PREVENTIVE DONEPEZIL TREATMENT FOR AMNESTIC MILD COGNITIVE IMPAIRMENT PATIENTS: LIFE- TIME MODEL

Djalalov S¹, Yong J¹, Saposnik G¹, Musa Z², Mendelson M³, Siminovich K⁴, Black S⁵, Hoch J²

¹St. Michael's Hospital, Toronto, ON, Canada, ²Cancer Care Ontario, Toronto, ON, Canada,

³Caledon Institute of Social Policy, Ottawa, ON, Canada, ⁴Mount Sinai Hospital, Toronto,

ON, Canada, ⁵Sunnybrook Health Sciences Centre, Toronto, ON, Canada

OBJECTIVES: Amnesic Mild Cognitive Impairment (AMCI) patients with Apolipoprotein e4 alleles (APOEe4), a type of genetic mutation, have higher rates of progression to Alzheimer Disease (AD) than patients without this genetic mutation. Some studies suggest that early diagnoses and treatment in APOE e4 carriers will delay their progression to AD. Objective is to evaluate the cost-effectiveness of APOEe4 testing in combination with preventive Donepezil treatment in AMCI patients in Canada. **METHODS:** We performed a cost-effectiveness analysis using a Markov model based on a formal literature review. The base case was assumed to be a 70-year-old AMCI individual with problems in the memory domain. The model used a societal perspective and a time horizon of 30 years. Two strategies were evaluated: genetic testing and preventive Donepezil treatment for APOEe4 gene carriers *vs.* no testing (the current standard of care in Canada). Outcome measures were quality-adjusted life years (QALYs), lifetime costs, and the incremental cost-effectiveness ratio (ICER). **RESULTS:** The genetic testing and Donepezil treatment combination strategy resulted in the gain of 0.047 QALYs, when compared to not testing. The Incremental cost was CAD \$ 1010 with Donepezil treatment; consequently, the ICER for the base case is estimated to be \$ 21,586. The prevalence of genetic mutations, cost of genetic test and cost of Alzheimer disease had a small effect on the cost-effectiveness results; however, the ICER is sensitive to AMCI utility, rate of progression to AD, AMCI surveillance cost, efficacy and cost of Donepezil preventive treatment. We conducted a sub-analysis by sex, and found that the ICER was lower for females than for males. **CONCLUSIONS:** Genetic testing in combination with preventive donepezil treatment for AMCI patients may be economically attractive in the current setting. Our preliminary findings are limited by substantial uncertainties surrounding the long-term efficacy of Donepezil preventive treatment and the rate of progression to AD.

TRANSLATIONAL AND POLICY RESEARCH IN PERSONALIZED MEDICINE FOR CANCER

Marshall DA¹, Kulin NA¹, Elkin EB², Ferrusi IL¹, Phillips K³

¹McMaster University, Hamilton, ON, Canada, ²Memorial Sloan-Kettering Cancer Center,

New York, NY, USA, ³University of California, San Francisco, CA, USA

Personalized medicine (PM) targets interventions to patients who are most likely to benefit based on genetic clinical markers or genomic information. There is little research on the translation of genomics into clinical practice and health policy; this lack of evidence on the use, effectiveness and efficiency of targeted technologies is a key challenge to their appropriate adoption and utilization. Our conceptual approach to translation of PM research into practice incorporates utilization, patient and provider preferences, and health economic evaluation in breast (BC) and colorectal cancer (CRC). We are documenting testing and treatment patterns in Canadian and US patients, including which patients receive testing, with which test(s) and test sequencing when confirmatory testing is performed. We are also measuring patient and provider preferences with discrete choice experiments to understand choice tradeoffs for testing and treatment. In the third component of our research program, we are using decision-analytic modeling methods to evaluate the sequelae of test-treat options. This analytical framework will characterise the cost-effectiveness of targeted therapy to estimate the value of PM interventions. Using our utilisation data, we will also